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USDA Options for Regulatory Changes to Enhance the Prevention and Control of Avian Influenza

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SUMMARY. During the past decade, several examples of the ability of H5 and H7 low-pathogenicity avian influenza (LPAI) viruses to mutate to high-pathogenicity (HP) viruses have been documented worldwide. During this time, the introduction and persistence of an H7N2 LPAI virus in the northeast live-bird marketing system in the United States has raised concern on how to prevent the possibility of such a mutation occurring in this country. The United States has periodically experienced trade restrictions based on the occasional introduction of H5 and H7 LPAI viruses into commercial poultry and based on AI-related changes in the import requirements for poultry and poultry products of several of our trading partners. Consequently, the U.S. Department of Agriculture (USDA) is exploring options for how our regulatory response to H5 and H7 LPAI viruses might be revised to better protect our domestic poultry flocks from HPAI and to ensure that any interruptions in trade are scientifically supportable. The options under consideration include mandatory and voluntary measures to improve the surveillance for and control of H5 and H7 LPAI virus infections.

RESUMEN. Opciones del Departamento de Agricultura de Estados Unidos (USDA) sobre los cambios en las regulaciones para mejorar la prevención y el control de la influenza aviar.

Durante la década pasada se han documentado a nivel mundial varios ejemplos relacionados con la capacidad de los virus de influenza de baja patogenicidad subtipos H5 y H7 para mutar a virus de alta patogenicidad. Durante este tiempo, la introducción y persistencia de un virus de baja patogenicidad H7N2 en mercados de aves vivas en el Noreste de los Estados Unidos a incrementado la preocupación acerca de como prevenir la posibilidad de que una mutación de éste tipo ocurra en éste país. Los Estados Unidos han experimentado periódicamente restricciones al comercio basadas en la introducción ocasional en la avicultura comercial de virus de baja patogenicidad subtipos H5 y H7 y basadas también en cambios en los requerimientos de importación para aves y productos avícolas de varios de nuestros socios comerciales, considerando los cambios en el virus de influenza aviar. Consecuentemente, el Departamento de Agricultura de los Estados Unidos está explorando opciones de la forma para revisar las regulaciones para virus de baja patogenicidad subtipos H5 y H7, con el fin de proteger mejor a nuestras parvadas contra la influenza aviar de alta patogenicidad y para asegurar que cualquier interrupción en el comercio tenga sustento científico. Las opciones bajo consideración incluyen medidas voluntarias y obligatorias para mejorar la vigilancia epidemiológica y el control de las infecciones con virus H5 y H7.

Key words: avian influenza, USDA, regulations, surveillance, live-bird markets

Abbreviations: AI = avian influenza; CFR = code of federal regulations; EC = European Commission; H = hemagglutinin; HPAI = high-pathogenicity avian influenza; LPAI = low-pathogenicity avian influenza; NPIP = National Poultry Improvement Plan; OIE = Office International des Epizooties; USDA = United States Department of Agriculture

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The Office International des Epizooties (OIE) defines high-pathogenicity avian influenza (HPAI) as a list A disease, requiring immediate notification to OIE should an outbreak occur in a member country (16). The European Commission (EC) and the U.S. Department of Agriculture (USDA) also define HPAI as a disease for which a federal stamping out program would be instituted in the event of such an outbreak (5,24). In contrast, none of these three governing bodies currently identifies low-pathogenicity avian influenza (LPAI) as a reportable disease or a disease for which federal action is undertaken.

The USDA is currently considering options for strengthening the ability of the United States to detect, prevent, and control H5 and H7 LPAI virus infections in both the live-bird marketing system and the commercial poultry system. For the purposes of this paper, these two systems or compartments are defined here: the live-bird marketing system includes the producers, dealers, auction markets, wholesalers, and retail markets engaged in the sale of live poultry or poultry slaughtered on demand to the consumer. The commercial poultry system includes the broiler, layer, and turkey breeder and production flocks from which meat and eggs are derived for domestic and international sale.

AVIAN INFLUENZA (AI) SURVEILLANCE IN THE UNITED STATES

The United States uses a combination of active and passive surveillance for AI. Passive surveillance is conducted through state and university diagnostic laboratories. These laboratories routinely test for AI, both serologically and by virus isolation, whenever birds are submitted from a flock with clinical signs compatible with HPAI or LPAI. Positive and suspicious samples are sent to the USDA National Veterinary Services Laboratories in Ames, IA, for confirmation. Clinical signs compatible with HPAI are also immediately reported to a federal veterinarian trained as a foreign animal disease diagnostician for further investigation.

Active surveillance is conducted in three settings. First, the National Poultry Improvement Plan (NPIP; a federal–state–industry cooperative program) has established an avian influenza clean certification program for AI surveillance in chicken breeding flocks in order to facilitate the export of hatching eggs and chicks from the United States (25). All flocks tested since this program began in 2000 have been negative.

Second, in recent years a number of broiler and turkey meat producers have been conducting AI serology tests on samples collected from their flocks just prior to slaughter to meet the requirements for export of poultry meat to Mexico (9). All flocks tested since Mexico established this requirement have been negative.

Third, several states have established AI surveillance programs, based on the risk of AI exposure unique to their states or regions. For example, Minnesota has established an AI surveillance program for range-reared turkeys (7); Texas established a surveillance program for commercial poultry flocks near the Mexican border, following the Mexican HPAI outbreak in 1994–95; and Pennsylvania, New York, and New Jersey have ongoing surveillance programs in live-bird markets and their supply flocks as a result of LPAI infections that persist in that marketing system (10).

Taken together, the current system of AI surveillance in the United States, while not centrally coordinated, provides a risk-based and needs-based approach to AI surveillance.

CURRENT FEDERAL REGULATIONS REGARDING AI CONTROL

The U.S. code of federal regulations (CFR) contains a three-part definition of HPAI that is similar to the OIE definition (15,24). The CFR defines HPAI as any AI virus that kills at least six of eight 4- to 6-week-old inoculated, susceptible chickens; any H5 or H7 virus that has an H cleavage site amino acid sequence compatible with other HPAI viruses; or any non-H5 or non-H7 virus that kills less than six inoculated chickens and grows in cell culture in the absence of trypsin. The CFR does not define LPAI.

The USDA has the authority to cooperate with state authorities in the control and eradication of HPAI and will pay "up to 100% of the expenses of purchase, destruction and disposition of animals and materials required to be destroyed because of being contaminated by or exposed to such disease" (24). The CFR does not carry such a specific authority for the control of LPAI infections. However, the CFR does permit the USDA to cooperate with state authorities in the control and eradication of "any communicable disease of livestock or poultry that in the opinion of the Secretary [of Agriculture] constitutes an emergency and threatens the livestock or poultry of the United States." If used in the case of LPAI, such an emergency declaration would likely precipitate an

embargo of U.S. poultry exports by our trading partners. Consequently, this emergency authority has not been employed for the control of LPAI infections, and LPAI control has, therefore, been viewed by the USDA as a state responsibility.

FACTORS MOTIVATING POSSIBLE REGULATORY CHANGES

Three factors suggest that increased USDA activity in H5 and H7 LPAI detection, prevention, and control is appropriate:

LPAI mutation potential. Evidence continues to accumulate that LPAI viruses of the H5 or H7 subtype, if permitted to circulate in poultry populations, can mutate to HPAI viruses. This occurred in Pennsylvania (H5N2 in 1983), Mexico (H5N2 in 1994), and Italy (H7N1 in 1999) (3,8,18). As a result of these occurrences, the EC reports that it is currently considering the option of including H5 and H7 LPAI infections in its statutory definition of AI and is also considering the appropriate regulatory response, including the use of vaccines, that such infections would merit (6).

Occurrence of AI in live-bird markets. LPAI viruses have been isolated in the live-bird marketing system in the northeast United States in recent years (17). Of particular concern are the H7N2 viruses that have been present in the markets of New York and New Jersey since 1994. These viruses have been characterized as low-pathogenicity viruses. However, the amino acid sequences of the hemagglutinin (H) proteins from some of these viruses have been found to carry more than two basic amino acids adjacent to the H cleavage site, raising concern that additional mutations could result in a highly pathogenic virus (19). Control efforts by the states of New York, New Jersey, and Pennsylvania, with coordination by the USDA, have yet to reduce the prevalence of these infections in the markets (11). Furthermore, commercial poultry farms in Pennsylvania (1997–98 and 2001–02), Connecticut (2001), and Virginia (2002) have experienced infections with the H7N2 viruses. Molecular analysis of these AI viruses suggests a link to the live-bird marketing system.

Trade problems related to AI. The United States is the world's largest exporter of broiler meat (23). In recent years, several trade problems associated with AI have resulted in the embargo of overseas shipments of U.S. poultry meat. Some of these embargos have been associated with the presence of the H7N2 LPAI viruses in the northeast United States as discussed above (e.g., embargos by China and Japan in 2001–02). Additionally, the USDA has observed that some trading partners now require a greater level of assurance that neither HPAI nor LPAI exist in source flocks. For example, Mexico's AI regulation (9) stipulates that source flocks must be tested for AI within 15 days of slaughter as a requirement for the importation of chicken and turkey meat into Mexico.

REGULATORY GOALS AND OPTIONS FOR LPAI CONTROL AND PREVENTION

Regardless of the size of a producer's operation or the intended market for his or her product, the goal of any disease control and prevention program should be to help the individual produce and market a product that is healthy, does not pose a human or animal health risk, and is acceptable in national and international markets. For LPAI, the means by which this goal is accomplished and the challenges that must be overcome in achieving this goal vary depending on the poultry population or compartment being considered.

Compartment 1: the live-bird marketing system. Three areas of the United States have significant live-bird marketing systems: the northeastern states (centered in New York City), Florida, and California (4). Based on the outdoor rearing practices and market delivery practices used by many participants in this system, poultry in this setting stand a high risk of exposure to LPAI viruses from the wildlife reservoir. The ongoing problems with H7N2 infections in the live-bird marketing system in the northeast and the isolation of other LPAI viruses in similar settings provide supporting evidence for this statement (17).

The USDA has two goals for this marketing system: to control the current LPAI problem in the northeastern United States and to prevent the reestablishment of H5 or H7 LPAI viruses in the live-bird marketing system. The USDA is currently assisting the northeastern states in their efforts to reduce the prevalence of H7N2 LPAI in the live-bird marketing system. These ongoing efforts include an epidemiology study (1,2) and closure, cleaning, and disinfection of live-bird retail markets that are positive for H7N2 LPAI. Therefore, here we discuss four long-term options for preventing further introductions of LPAI viruses into the U.S. live-bird marketing system:

1. Prohibit a live-bird marketing system in the United States. Some have suggested to the USDA that this is

a desirable approach to the prevention and control of AI infections. The USDA does not view this as a viable or enforceable option, however. Should the USDA attempt to impose such a restriction? The cultural preferences of consumers would create an underground market for such poultry.

2. Prohibit the interstate movement of AI-positive poultry. This option would establish a federal requirement for the use of individual bird identification, AI testing, and record keeping in all production, distribution, and retail operations of the live-bird marketing system, with trace back and indemnification when positive AI test results are obtained. (Commercial poultry moving across state lines en route to a slaughter plant would need to be exempt from such a requirement.) Provided it is adequately enforced, such a control program would have the advantages of reducing the risk of LPAI transmission nationwide (rather than regionally) and reducing some of the responsibility and cost of LPAI control currently borne by individual states. Conversely, this option could be viewed as an unnecessary regulation in areas that have not historically experienced problems with LPAI.

3. Establish an AI certification program. Using the NPIP model currently in place for certifying breeding chickens as free of AI, an AI-free program could be established for live-bird market and supplier facilities. Such a program could require participants to use individual bird identification tags, to use regular testing of birds and facilities for AI, and to follow specific sanitation and biosecurity guidelines. Indemnification could be made part of such a program for participating facilities that are found to be positive for H5 or H7 LPAI, provided they are otherwise adhering to the program requirements. While participation in such a program would likely be voluntary from a federal viewpoint (if the current NPIP structure is used), states such as those in the northeast with a history of LPAI infections could require through their regulations that producers, dealers, and marketers within their state participate in the federal program. This option has the advantage of improving on the current state rules in New York and New Jersey (the only states with regulations governing the live-bird retail markets [13,14]) by enhancing enforcement through the use of individual bird identification tags and record keeping. While this option would create a focused, state-by-state approach to controlling LPAI, it could fail to include states that may have currently unidentified LPAI infections in their live-bird marketing systems.

4. Encourage the states to develop more aggressive H5 and H7 LPAI control programs. Because LPAI is currently considered a state responsibility, the USDA must also consider the option of leaving the current federal regulations unchanged. Some states may believe that this option is more attractive than USDA intervention and that it has the advantage of allowing states to tailor H5 and H7 LPAI control programs to meet the needs of their specific poultry industries. A strong control or certification program that includes individual bird identification, a concerted enforcement effort, and indemnification for positive facilities (such as that described in the previous paragraphs) has yet to be attempted by any state.

Compartment 2: the commercial poultry system. In the United States, with the exception of range-reared turkeys, this poultry population is raised in enclosed housing and has a very low risk of exposure to AI infections. The absence of positive AI test results either from blood samples collected to satisfy the Mexican poultry meat import requirements or from blood samples collected in the NPIP AI breeder flock program provides supporting evidence for this statement. However, this low risk of exposure is not uniform throughout the entire U.S. poultry industry. Occasional LPAI infections have occurred on commercial poultry farms that also conduct trade within the live-bird marketing system or on farms that are located in close proximity to other facilities that engage in such trade. The majority of birds sold in live poultry markets in the New York City metropolitan area are broilers and spent laying hens, some of which are derived from large commercial poultry flocks. Therefore, if changes to the current AI surveillance and control activities are to be designed for commercial poultry flocks, those changes will need to be based on the risk of AI exposure.

The USDA has two goals for the commercial poultry system: to prevent, detect, and control the introduction of H5 and H7 LPAI into commercial poultry flocks and to certify freedom from H5 and H7 LPAI to facilitate international trade. Below we discuss four options for achieving these goals:

1. Supplement the current surveillance system with stamping out and indemnification. The decentralized AI surveillance system discussed earlier has evolved over time based on the needs of the industry and the risk of exposure to AI. This system serves the United States well for detecting HPAI infections. However, what is lacking in this system is a clear course of action when an H5 or H7 LPAI virus is isolated in

a commercial flock. The USDA could revise its regulations to allow for the stamping out of H5 and H7 LPAI infected flocks with indemnification for destroyed animals and material. This is similar to the redefinition of AI under consideration by the EC. This approach would likely be welcomed by state and industry officials because it would not create additional federal requirements but would provide financial support for state LPAI control efforts.

2. Create a mandatory, nationwide surveillance system with stamping out and indemnification. The current AI surveillance system has the potential to allow some H5 and H7 LPAI infections to go undetected. It could be possible for the USDA to develop a system for nationwide random flock selection and testing for AI. Such a mandatory surveillance and control program could include biosecurity requirements to reduce the chance of exposure to AI and could include stamping out with indemnification for flocks found to be positive for H5 or H7 LPAI. Such a program would have the advantage of providing our trading partners with the best assurance that H5 and H7 LPAI and HPAI do not exist in commercial U.S. poultry flocks. However, because the United States produces over 8 billion broiler chickens, 277 million table egg laying hens, and 270 million turkeys annually (22,21), such a mandatory random surveillance system would be a massive, costly undertaking. Also, it could be argued that such an approach may not be necessary in areas or facilities with low risk of AI exposure.

3. Establish a voluntary certification program with stamping out and indemnification. Using the NPIP program as a model, a voluntary certification program could be developed to demonstrate the absence of H5 or H7 LPAI in a given flock or facility and to stamp out and indemnify any participating flock found to be positive. This approach has the advantage of expanding the current LPAI surveillance and control activities based on AI risk and industry needs. Participation in such a program would be most attractive to producers with facilities at risk of AI exposure (e.g., the northeast United States) and to producers of chicken and turkey meat for export (e.g., to meet the current Mexican regulations). Such a program would build upon the respect already carried by the NPIP program in the international marketplace. A disadvantage to this approach, however, is that it may be viewed as an incomplete program by trading partners who have or are planning nationwide AI surveillance systems.

4. Encourage states to set up their own surveillance and stamping out programs. As discussed earlier, LPAI control is currently a state responsibility. Some states may wish to retain that authority. No state, however, has yet established a standing LPAI stamping out and indemnification program.

THE ROLE OF AVIAN INFLUENZA VACCINES

USDA regulations and guidelines permit the development, licensure, and production of vaccines against all 15 H subtypes of avian influenza (12). Currently, a live pox virus recombinant vaccine and a killed virus vaccine are licensed for vaccination against H5 infections, and a killed virus vaccine could be approved on an emergency basis for vaccination against H7 infections. However, the USDA only permits the use of H5 and H7 vaccines as part of an official USDA control program (20). Therefore, while these vaccines have been developed, they have been used rarely in U.S. flocks.

As the USDA considers widening the scope of its AI control activities to include H5 and H7 LPAI infections, we will need to consider the role vaccines might play in any such program. While H5 and H7 AI vaccines can prevent HPAI clinical signs and can reduce challenge virus shedding, these vaccines carry the following limitations: efficacy studies using an LPAI challenge (as opposed to the standard HPAI challenge) have not been developed and standardized; killed AI virus vaccines typically interfere with serologic surveillance for AI, requiring the use of sentinel birds for flock monitoring; the use of AI vaccines to control LPAI may precipitate poultry embargos by our trading partners; and the currently licensed vaccines are not approved for use in all the poultry species found in the live-bird markets.

Currently, the most feasible use of H5 and H7 AI vaccines appears to be as an adjunct to the quarantine, depopulation, cleaning, disinfection, and biosecurity measures necessary to control an AI outbreak. For example, vaccination could be conducted in flocks (particularly breeding stock) within a buffer zone or ring around an active outbreak and in replacement flocks after outbreak control activities have been completed. However, in the absence of clinical signs or the designation of LPAI as a reportable disease, the use of these vaccines as an aid in the control of LPAI infections will need to be considered cautiously, on a case-by-case basis.

In conclusion, we have identified several options for bringing a greater degree of prevention, detection, and control of LPAI infections to both the live-bird marketing system and the commercial poultry system. No doubt there are other options

not included in this paper that could be suggested by our USDA customers and stakeholders. In the coming months, the USDA will be actively seeking input and suggestions from states, the live-bird and commercial poultry industries, and the general public on what course of action, if any, we should take with regard to H5 and H7 LPAI infections.

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